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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,969	07/21/2005	Tomoharu Suga	236276-000003	2010
84310	7590	08/06/2010		
Troutman Sanders LLP The Chrysler Building 405 Lexington Avenue New York, NY 10174			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 08/06/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Ellen.Walters@troutmansanders.com  
patents@troutmansanders.com  
james.schutz@troutmansanders.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,969	<b>Applicant(s)</b> SUGA ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

- Receipt is acknowledged of applicants' appeal brief, filed on 16 April 2010.
- After further consideration, finality of the previous Office action is hereby withdrawn.
- Applicants' arguments have been considered but are moot in view of the new grounds of rejection.

\* \* \* \* \*

### ***Status of the Claims***

Claim 1 has been cancelled. Claims 2-10 are under active prosecution and are rejected.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 361 874 ("KOYAMA") (see IDS filed on 21 July 2005).

Independent claim 6 claims an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core and a coating of a pharmaceutically acceptable disintegrating agent substantially completely covering said core to form a granule. Independent claim 7 differs from independent claim 6 sugar is not explicitly listed as an ingredient that is added to the core.

KOYAMA discloses rapidly disintegrating spherical granules (see, e.g., page 2, line 38) which are spray coated with low substituted hydroxypropyl cellulose (see, e.g., page 2, line 39), reading on claims 2, 6, 7, and 8.

The core may be comprised of sucrose (see page 2, line 53) and an active agent (see page 2, line 54), reading on claims 3, 6, and 7. KOYAMA uses a CF granulator in a granulation process to spray a solution comprising low substituted hydroxypropylcellulose onto the core to form a coating (see page 2, lines 39-43). Such a process inherently results in substantially complete covering of a core to form a granule, reading on claims 6 and 7. The disclosed disintegrating agent coated granules may be compressed into tablets with a thickness of 8.4 mm (see Example 2), reading on claims 5-7 and 10.

Regarding claim 7, while KOYAMA does not disclose a core comprising active agent alone, the core disclosed by KOYAMA reads on claim 7 as currently constructed because claim 7 uses the open transition phrase "comprising" and thus does not preclude inclusion of agents other than a water soluble active ingredient (such as sucrose) to the claimed core.

Regarding the limitation "intraorally rapidly disintegrating tablet", as currently claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. *In re Fitzgerald*, 205 USPQ 594.

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 361 874 ("KOYAMA").

KOYAMA is discussed in-part above.

Regarding claims 4 and 9, KOYAMA teaches a particle size between 12 (1,400 micrometers) and 32 (500 micrometers) mesh (see, e.g., page 3, line 57). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core and a coating of a pharmaceutically acceptable disintegrating agent substantially completely covering said core to form a granule, as taught by KOYAMA. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in granules with increased granule strength and rapid disintegration, as explained by KOYAMA (see page 2, line 38).

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner  
Art Unit 1615